REMARKS

I. Status of the Claims

Claim 1 as currently amended includes all limitation of the original claims 2 and 3 with the narrower range of the amount of the thrombin. No new matter has been added. Hereby the non-elected claims 7-12 have been canceled. However, applicants reserve the right to file the divisional application. Claims 1 and 5 ~ 6 are pending.

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 stand rejected under 35 U.S.C. 102(b) as being anticipated by Glorioso (US Pat. 6,413,511).

Claims 1, 2, 4, and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by Itay (US Patent 4,904,259).

Claims 1 to 2 and 4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti (WO 96/03160).

Claim 1 to 4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Passaretti et al, (*Tissue Engineering,*).

Claims 1 to 6 stand rejected under 35 U.S.C. 103(a) as allegedly obvious over Passaretti et al, in view of Liu (US Patent 5,972,385).

Claims 1 to 6 stand rejected under 35 U.S.C. 103(a) as allegedly obvious over Passaretti et al/ Liu (US Patent 5,972,385) and further in view of Petito (US patent application publication 2002/0025921).

II. Regarding the Claim Rejection under 35 U.S.C. §112:

Claim 5 has been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The Office Action alleges "The use of the word "such as" is indefinite. Applicants have deleted "such as" from claim 5 to advance prosecution of the present application.

III. Regarding the Claim Rejection under 35 U.S.C. §102 (b):

Claims 1 and 2 were rejected under 35 U.S.C. § 102(b) as being anticipated by Glorioso (US Pat. 6,413,511).

Claim 1 has been amended to provide the narrower range of the thrombin usage such as ***0.01 IU/ml -50 IU/ml.*** Therefore claim 1, as presented, should be overcome the rejection of Glorioso.

Claims 1, 2, 4, and 6 stand rejected under 35 U.S.C. 102(b) as being anticipated by Itay (US Patent 4,904,259). This rejection is respectfully traversed.

Anticipation under Section 102 of the Patent Act requires that a prior art reference disclose every claim element of the claimed invention. See, e.g., *Orthokenetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1574 (Fed. Cir. 1986).

Itay fails to disclose every claim element of the currently amended claimed invention. For example, Itay fails to show the specific range of the amount of the thrombin in the composition. Itay states in Col 2, lines 44-50;

> A biological resorbable immobilization vehicle (BRIV) in the composition comprises about 15-30% serum, 100-150 mg/ml of fibrinogen, **60-90 units/ml thrombin,** 60 mM calcium chloride ($CaCl_2$) and 2000 units/ml (KIU) aprotonin ***(Emphasis added)***.

Itay uses 60-90 units/mL thrombin while the instant invention uses 0.01 IU/mL to 50 IU/mL of thrombin. Although the rejections are not necessarily agreed with, to facilitate matters claim 1 has been amended herein to include the features of cancelled claims 2, 3 and 4. More specifically, the limitation of ***the amount of thrombin is more than 2 IU/mL, but less than 50 IU/mL.*** Therefore claim 1, as presented, should be overcome the rejection of Itay.

Claims 1 to 2 and 4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Vacanti (WO 96/03160).

Claim 1 has been amended to provide the narrower range of the thrombin usage such as ***0.01 IU/ml -50 IU/ml.*** Therefore, the currently amended claim 1, as presented, should be overcome the rejection of Vacanti.

Claim 1 to 4 stand rejected under 35 U.S.C. 102(b) as being anticipated by Passaretti et al, (*Tissue Engineering,*).

Claim 1 has been amended to provide the narrower range of the thrombin usage such as ***0.01 IU/ml -50 IU/ml.*** Therefore, the amended claim 1, as presented, should be overcome the rejection of Passaretti.

IV. Regarding the Claim Rejection under 35 U.S.C. §103 (a):

The ground rejection of claims 1-6, under 35 U.S.C. §103(a) as being unpatentable over Passaretti et al, in view of Liu (US Patent 5,972,385) is respectfully traversed.

In order to establish a prima facie case of obviousness, the references cited by the Examiner must disclose all claimed limitations. *In re Royka,* 490 F.2d 981,180 U.S.P.Q. 580 (C.C.P.A. 1974). Even if each limitation is disclosed in a combination of references, however, a claim composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int 'L v. Teleflex Inc.,* 127 S.Ct. 1727, 1741 (2007). Rather, the Examiner must identify an apparent reason to combine the known elements in the fashion claimed. *Id* "Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *Id.,* citing *In re Kahn,* 441 F.3d 977, 988 (Fed. Cir. 2006).

Finally, the reason must be free of the distortion caused by hindsight bias and may not rely on ex post reasoning. *KSR,* 127 S.Ct. at 1742. In addition, evidence that such a combination was uniquely challenging or difficult tends to show that a claim was not obvious. *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. and Mattel, Inc.,* 485 F.3d 1157, 1162 (Fed. Cir. 2007), citing *KSR,* 127 S.Ct. at 1741.

Applicants have amended the independent claim 1 to advance prosecution in a timely manner, to further distinguish from Passaretti and Liu. More specifically, claim 1 as amended recites in part:

> wherein the thrombin is used **more than 2 IU/mL, but less than 50 IU/mL,**

The examiner asserted that Passaretti teaches a tissue-engineered cartilage composition comprising isolated autologous chondrocytes (40x106 cells/mL), fibrinogen (80 to 160 mg/mL), and thrombin (50 units/mL i.e. 50 IU/mL). Liu teaches a matrix or the support of cartilage repair in the form of a fibrin-collagen tissue equivalent which comprises 20mg/mL collagen, 20mg/mL fibrinogen and 2U/mL of thrombin. From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In order to distinguish from the teaching of Passaretti and Liu, claim 1 has been amended herein to include the features of claims 2, 3 and 4. More specifically, ***the use of the amount of the thrombin is narrowed such as more than 2 IU/m, but less than 50 IU/mL.*** Thus, the combination of Passaretti and Liu would be failed to teach the use of "**the thrombin more than 2 IU/mL, but less than 50 IU/mL**" as amended.

In view of the foregoing, claim 1 defines over the prior art. Therefore, reconsideration and withdrawal of the rejections are respectfully requested. Each of claims 5 - 6 ultimately depend from claim 1, which defines over the prior art, as discussed in detail above.

Therefore, each of claims 5 - 6 also defines over the prior art for at least the same reasons, and reconsideration and withdrawal of the rejections are respectfully requested.

The ground rejection of claims 1-6, under 35 U.S.C. §103(a) as being unpatentable over Passaretti et al/ Liu (US Patent 5,972,385) and further in view of Petito (US patent application publication 2002/0025921) is also respectfully traversed.

In order to distinguish from the teaching of Passaretti and Liu, claim 1 has been amended herein to include the features of claims 2, 3 and 4. More specifically, ***the use of the range of the amount of the thrombin is narrowed such as more than 2 IU/m, but less than 50 IU/mL.*** Thus, the combination of Passaretti and Liu would be failed to teach the use of **"the amount of the thrombin more than 2 IU/mL, but less than 50 IU/mL"** as amended.

The examiner admitted that the combination of Passaretti et al, 2001 and the Liu patent does not expressly teach the presence an antibiotic or antifungal agent but this deficiency is cured by the teachings of the Petito publication because the Petito publication teaches a collagen composition for cartilage repair. The Pettito publication also teaches the incorporation of antibiotics such as streptomycin in the composition.

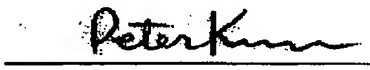
Since claim 1 has been amended herein to include the features of claims 2, 3 and 4, more specifically, the use of the range of the amount of ***the thrombin is narrowed such as more than 2 IU/mL, but less than 50 IU/mL.*** Thus, the combination of Passaretti/Liu and Petito would be failed to teach such a limitation of **"more than 2 IU/mL, but less than 50 IU/mL of thrombin"** as amended.

In view of the foregoing, claim 1 defines over the prior art. Therefore, reconsideration

and withdrawal of the rejections are respectfully requested. Each of claims 5 - 6 ultimately depend from claim 1, which defines over the prior art, as discussed in detail above. Therefore, each of claims 5 - 6 also defines over the prior art for at least the same reasons, and reconsideration and withdrawal of the rejections are respectfully requested.

Thus, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance are earnestly solicited.

Respectfully submitted



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